MENSTRUAL COMPLETE MAXIMUM STRENGTH- acetaminophen, caffeine and pyrilamine maleate tablet, film coated

L.N.K. International, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Quality Plus 44-390

Active ingredients (in each caplet)

Acetaminophen 500 mg Caffeine 60 mg Pyrilamine maleate 15 mg

Purpose

Pain reliever Stimulant Diuretic

Uses

- for the temporary relief of these symptoms associated with menstrual periods:
- cramps
- bloating
- water-weight gain
- headache
- backache
- breast tenderness
- fatigue
- muscle aches

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Do not use

• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

• taking the blood thinning drug warfarin

taking sedatives or tranquilizers

When using this product

- you may get drowsy
- be careful when driving a motor vehicle or operating machinery
- avoid alcoholic drinks
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat. The recommended dose of this product contains about as much caffeine as a cup of coffee.

Stop use and ask a doctor if

- new symptoms appear
- redness or swelling is present
- pain gets worse or lasts more than 10 days

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than the recommended dose (see Overdose warning)
- adults and children 12 years and older: take 2 caplets with water. Repeat every 6 hours, as needed.
 Do not exceed 8 caplets in 24 hours.
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store at controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silica gel, stearic acid, titanium dioxide, triacetin

Questions or comments?

1-800-426-9391

Principal Display Panel

QUALITY PLUS

NDC 50844-390-21

*Compare to the active ingredients in Midol® Complete

MAXIMUM STRENGTH

Menstrual Complete

Acetaminophen, Caffeine, Pyrilamine maleate

PAIN RELIEVER / STIMULANT / DIURETIC

MULTI-SYMPTOM RELIEF OF:

Cramps, Bloating, Fatigue, Backache & Headache

16 Caplets

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark $Midol^{\$}$ Complete.

50844 ORG081039021

Distributed by **LNK INTERNATIONAL, INC.** 60 Arkay Drive Hauppauge, NY 11788 USA

symptoms associated with menstrual periods: ■ for the temporary relief of these Diuretic. Pyrilamine maleate 15 mg. Caffeine 60 mg. Stimulant. stnəibərgni əvitəA (təlqsə dəsə ni) Purpose

acetaminophen. Severe liver damage may occur if Liver warning: This product contains

augitst = wnzcje scpez ■ backache ■ breast tenderness

Drug Facts (continued)

Warnings

исведасив enitsold = ■ cusmps

SETAIN CARTON FOR COMPLETE

Drug Facts

9

n 33

#

08

I

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

MAXIMUM STRENGTH

strual Comple

Acetaminophen, Caffeine, Pyrilamine maleate

PAIN RELIEVER / STIMULANT / DIURETIC

MULTI-SYMPTOM RELIEF OF:

Cramps, Bloating, Fatigue, Backache & Headache

16 Caplets

■ children under 12 years: do not use this adult needed. Do not exceed 8 caplets in 24 hours caplets with water. Repeat every 6 hours, as adults and children 12 years and older: take 2 recommended dose (see Overdose warning)

or symptoms.

Dung Facts (continued)

QUALITY P

m water-weight gain

Drug Facts (continued

croscarmellose sodium, crospovidone, polyethylene glycol, povidone, silica microcrystalline cellulose, polydextrose nypromellose, magnesium stearate Inactive ingredients com starch

Questions or comments?

1-800-426-9391

triacetin

gel, steamo

UISTITUTED by
LINK INTERNATIONAL, INC.
60 Arkay Drive
Hauppauge, NY 11788
USA by Bayer HealthCare LLC, owner of the registered trademark Midol® Complete. 50844 ORG081039021 This product is not manufactured or distributed

Boyor Graphics

 excitability may occur, especially in children operating machinery a svoid alcoholic drinks

■ be careful when driving a motor vehicle or When using this product woy yet drowsy

■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin

Ask a doctor or pharmacist before use if you are

chronic bronchitis

glaucoma

 s preathing problem such as emphysema or ■ liver disease prostate gland

 qitticulty in unination due to enlargement of the Ask a doctor before use if you have

a doctor or pharmacist. sure whether a drug contains acetaminophen, ask

(prescription or nonprescription). If you are not with any other drug containing acetaminophen

this product

 3 or more alcoholic drinks every day while using ■ with other drugs containing acetaminophen

Innome ylieb mumixem ■ more than 8 caplets in 24 hours, which is the

Drug Facts (continued)

Directions - do not take more than the (overdose) and may cause liver damage will provide more than the recommended dose

Other information

(4.98-.6G)

product in children under 12 years of age; this

see end flap for expiration date and lot number

■ store at controlled room temperature 15-30°C

Drug Facts (continued)

B-1603-390-21 0RG08103902

> children even if you do not notice any signs medical attention is critical for adults as well as for contact a Poison Control Center right away. Quick damage. In case of overdose, get medical help or recommended dose (overdose) may cause liver Overdose warning: Taking more than the Keep out of reach of children.

professional before use.

If pregnant or breast-feeding, ask a health

These could be signs of a serious condition. ■ pain gets worse or lasts more than 10 days

m redness or swelling is present

new symptoms appear

Stop use and ask a doctor if catteine as a cup of coffee.

gose of this product contains about as much occasionally, rapid heartbeat. The recommended nervousness, irritability, sleeplessness, and, because too much caffeine may cause Jooqs' or peverages while taking this product

limit the use of caffeine-containing medications, alcohol, sedatives and tranquilizers may increase

Orug Facts (continued)

DG9038A



Quality Plus 390-21

MENSTRUAL COMPLETE MAXIMUM STRENGTH

acetaminophen, caffeine and pyrilamine maleate tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50844-390
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	60 mg
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
CROSPOVIDONE (UNII: 2S7830E561)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
PO VIDO NE (UNII: FZ989 GH94E)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	

Product Characteristics					
Color	WHITE	Score	score with uneven pieces		
Shape	OVAL	Size	17mm		
Flavor		Imprint Code	44;390		
Contains					

ı	Pac	kaging				
ı	#	Item Code		Package Description	Marketing Start Date	Marketing End Date
	1 NI	DC:50844-390-19	1 in 1 CARTON		04/29/2002	

1	8 in 1 BLISTER PACK; Type 0: Not a Combination Produ	t
2 NDC:50844-390-21	2 in 1 CARTON	04/29/2002
2	8 in 1 BLISTER PACK; Type 0: Not a Combination Produ	t
Marketing Inf	formation	
Marketing Inf		on Marketing Start Date Marketing End Da
	gory Application Number or Monograph Cita	on Marketing Start Date 04/29/2002 Marketing End Da

Labeler - L.N.K. International, Inc. (038154464)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(50844-390)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(50844-390)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(50844-390)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(50844-390)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(50844-390)

Revised: 11/2019 L.N.K. International, Inc.